EYE DROPS ADVANCED RELIEF- tetrahydrozoline hydrochloride, polyethylene glycol 400, dextran 70, povidone solution/ drops
Strategic Sourcing Services LLC

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Active ingredients

Dextran 70 0.1%

Polyethylene glycol 400 1%

Povidone 1%

Tetrahydrozoline HCl 0.05%

Purpose

Dextran 70.....Eye lubricant

Polyethylene glycol 400.....Eye lubricant

Povidone.....Eye lubricant

Tetrahydrozoline HCl.....Redness reliever

Uses

- relieves redness of the eye due to minor eye irritations
- as a lubricant to prevent further irritation or to relieve dryness of the eye

Warnings

For external use only

Ask a doctor before use if you have narrow angle glaucoma

When using this product

- pupils may become enlarged temporarily
- to avoid contamination, do not touch tip of container to any surface. Replace cap after using
- if solution changes color or becomes cloudy, do not use
- overuse may product increased redness of the eye
- remove contact lens before using

Stop use and ask a doctor if you experience

- eye pain
- changes in vision
- continued redness or irritation of the eye, or if the condition worsens or persists for more than 72 hours

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

If pregnant or breastfeeding, ask a health professional before use

Directions

Instill 1 or 2 drops in the affected eye(s)up to four times daily.

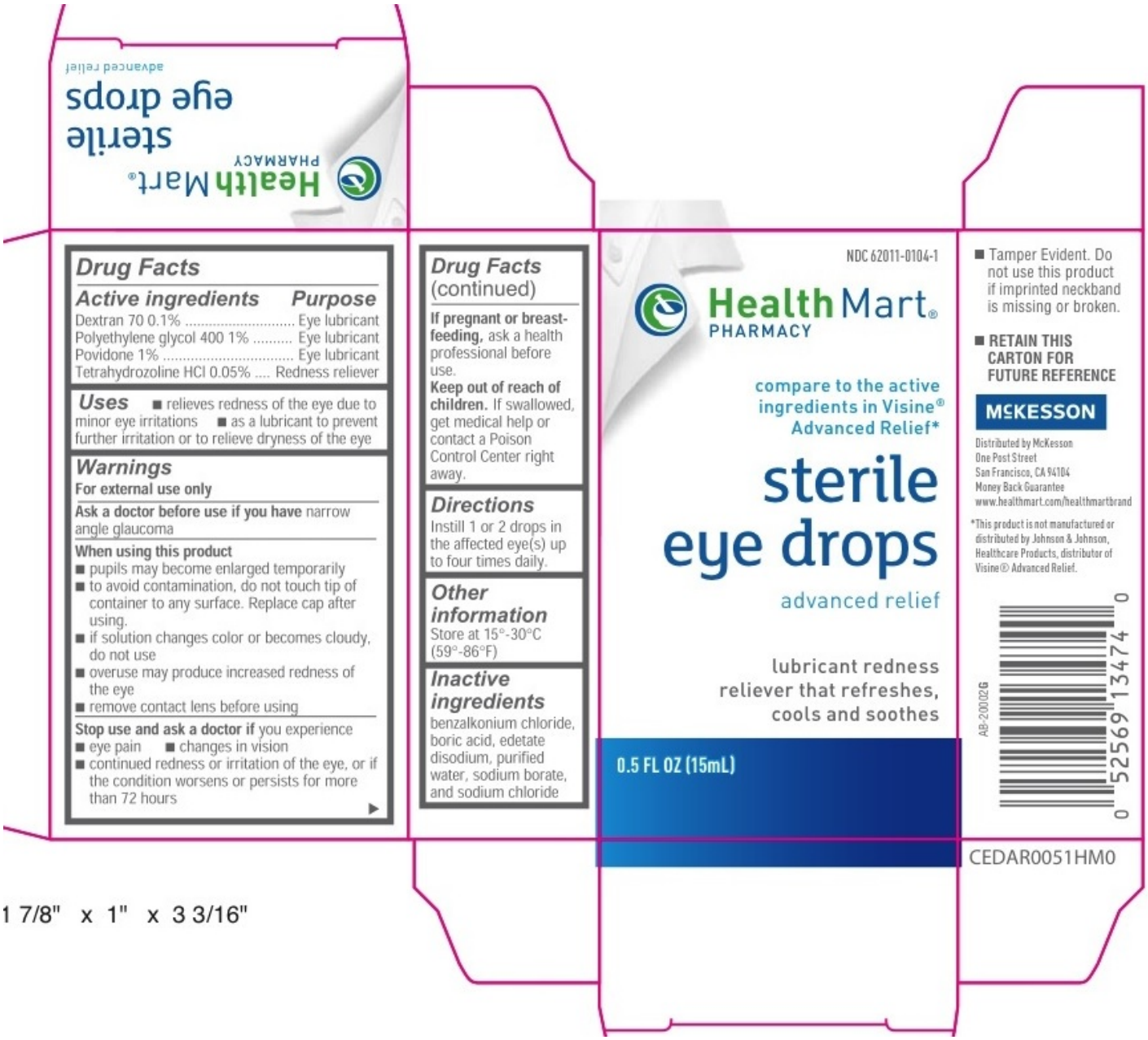
Other information

Store at 15º-30ºC (59ª-86ºF)

Inactive ingredients

benzalkonium chloride, boric acid, edetate disodium, purified water, sodium borate, and sodium chloride.

Carton HMEyeDrAdvRel.jpg



EYE DROPS ADVANCED RELIEF

tetrahydrozoline hydrochloride, polyethylene glycol 400, dextran 70, povidone solution/ drops

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:62011-0104
Route of Administration	OPHTHALMIC		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**

TETRAHYDROZOLINE HYDROCHLORIDE (UNII: 0YZT43HS7D) (TETRAHYDROZOLINE - UNII:S9U025Y077)	TETRAHYDROZOLINE HYDROCHLORIDE	0.5 mg in 1 mL
POVIDONE (UNII: FZ989GH94E) (POVIDONE - UNII:FZ989GH94E)	POVIDONE	10 mg in 1 mL
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ) (POLYETHYLENE GLYCOL 400 - UNII:B697894SGQ)	POLYETHYLENE GLYCOL 400	10 mg in 1 mL
DEXTRAN 70 (UNII: 7SA290YK68) (DEXTRAN 70 - UNII:7SA290YK68)	DEXTRAN 70	1 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
BORIC ACID (UNII: R57ZHV85D4)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
WATER (UNII: 059QF0KO0R)	
SODIUM BORATE (UNII: 91MBZ8H3QO)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62011-0104-1	1 in 1 CARTON	03/01/2012	
1		15 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part349	03/01/2012	

Labeler - Strategic Sourcing Services LLC (116956644)

Registrant - KC Pharmaceuticals, Inc. (174450460)

Establishment

Name	Address	ID/FEI	Business Operations
KC Pharmaceuticals, Inc.		174450460	manufacture(62011-0104) , pack(62011-0104) , label(62011-0104)

Revised: 9/2019 Strategic Sourcing Services LLC